

b.) Remarks

Claims 42, 44, 63, 64, 80 and 82 have been amended in order to recite the present invention with the specificity required by statute and claims 43, 45, 72, 81 and 83 are amended in conformity therewith. The subject matter of the amendment may be found in the specification as filed at page 10, lines 23-25. Accordingly, no new matter has been added.

Claims 42-53, 63-70 and 72-102 are rejected under 35 U.S.C. §112, first paragraph, because the Examiner contends the specification does not discuss the limitations made by the previous applicant's amendments. In support of the rejection the Examiner states the following limitations are not described in the specification as filed:

- coating film which is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm^2
- base matrix which is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm^2
- said molding material comprising same amount of said granule and said diluting agent
- said molding material is dry.

The rejection is respectfully traversed. Tablets in comparisons 7 and 8 experience damage of the film coated on the surface of the granule (see Tables 3 and 4 in Experiment 4) at tableting pressure of 1000kg/punch. This pressure is the same as 1.3 ton/cm^2 , because the tablets are produced by using tableting machine with 7mm diameter punch and die. Therefore, points 1 and 2 are supported by the description on page 14, lines 5-9, in view of Experiments 3 and 4 at pages 62-63 in the present specification.

Additionally, tablets in Experiments 3 and 4 are produced by mixing same amount of granule and diluting agents (lactose and crystalline cellulose), and the tablets are dry (see page 62, line 11 and page 62, line 8, “as dry type”).

Claims 42-53, 63-70 and 72-102 are rejected under 35 U.S.C. §103(a) as being obvious over Morimoto et al. (EP 0 650 826) in view of Roche (US 5,075,114). These claims are also rejected as being obvious over Tsushima et al. (US 6,036,974), in view of Roche.

The rejection too is respectfully traversed. As the Examiner is aware, Morimoto produces a tablet using a tableting machine with lubricant spraying means which can spray lubricant uniformly on the surface of an upper punch, a lower punch and a die, and Tsushima teaches preparing an aqueous tablet comprising 10% ethanol or water. Roche teaches that coated granules release medicament in the GI tract.

However, the references, even taken together, do not teach or suggest a tablet which does not contain stearic acid or a stearic acid metal salt but which contains 0.0001-0.2 wt% stearic acid or stearic acid metal salt on the surface.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 42-53, 63-70 and 72-102 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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